



UNITED STATES **ARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

M U

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/313,942 05/19/99 STAHL

N REG-203-A

HM22/0814

JOSEPH M. SORRENTINO, ESQ.  
VICE PRESIDENT, INTELLECTUAL PROPERTY  
REGENERON PHARMACEUTICALS, INC  
777 OLD SAW MILL RIVER ROAD  
TARRYTOWN NY 10591

EXAMINER

O HARA, E

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

08/14/00

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/313,942

Applicant(s)

Stahl et al.

Examiner

Eileen B. O'Hara

Group Art Unit

1646

 Responsive to communication(s) filed on Jun 8, 2000 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-25 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-25 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

## **DETAILED ACTION**

1. Claims 1-25 are pending in the instant application.

The restriction requirement made in Paper No.7 is hereby withdrawn. Therefore, all claims and all species of cytokine receptors will be examined.

### ***Information Disclosure Statement***

2. The last reference in the Information Disclosure Statement has not been considered because the submitted document was not properly identified (there was no cover sheet on the document identifying it).

### ***Drawings***

- 3.1 Figures 4 and 9 of the instant application are each presented on two separate panels. 37 C.F.R. § 1.84(U)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For example, the two sheets of drawings which are labeled "Figure 4" in the instant specification should be renumbered "Figures 4A and 4BC", as in Figures 21-26, 31 and 32. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment under 37 C.F.R. § 1.312 to change the Brief Description of the Drawings and the rest of the specification accordingly. If, for example, Figure 4 is divided into Figures 4A and 4B, then the

Art Unit: 1646

Brief Description and all references to this figure in the specification must refer to Figures 4A and 4B.

3.2 In Figure 27, "IL4RaFc" should be replaced with "IL4RaFcΔC1" to match the description on page 12, line 22 in the specification.

### ***Double Patenting***

4.1 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4.2 Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-8 of U.S. Patent No. 5,844,099. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fusion proteins claimed in the patent necessarily require possession of the nucleic acids encoding them.

Art Unit: 1646

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being obvious over Stahl et al., PN 5,844,099.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131.

Claims 1-25 encompass nucleic acid molecules encoding fusion polypeptides comprising the amino acid sequences of a cytokine binding portion of the extracellular domain of the specificity determining component of the cytokine's receptor, the cytokine binding portion of the extracellular domain of the signal transducing component of the cytokine's receptor, and a multimerizing component.

Art Unit: 1646

Stahl et al. disclose polypeptides comprising the specificity determining component of a cytokine's receptor, the cytokine binding portion of the extracellular domain of the signal transducing component of the cytokine's receptor, and an immunoglobulin derived domain (see Figures 7 and 19), and teach chimeric molecules using the Fc-domain of IgG (column 8, lines 17-58.

Since the fusion proteins of Stahl et al. necessarily require possession of the nucleic acids encoding them, the nucleic acid molecules of the present application are obvious over the proteins.

*Conclusion*

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

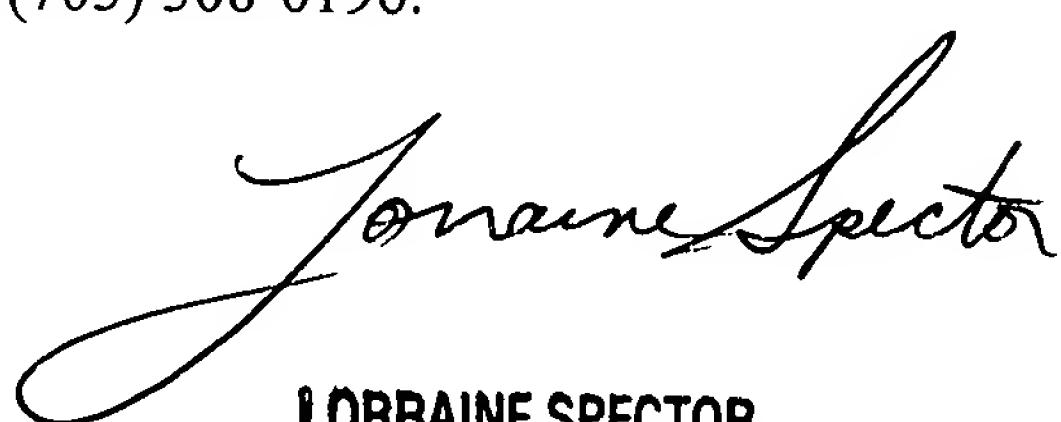
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER